

Serial No.: 09/413,012  
Docket No.: R0052CON  
Amendment Dated May 4, 2006  
Responsive to the Office Action dated March 6, 2006

#### REMARKS

Claims 34-71 remain pending. No amendments have been made.

In the Office Action, the Examiner again indicates that claims 36, 45, 51, 54, 61, and 67-71 are withdrawn from further consideration as being drawn to non-elected species. Although Applicants believe that some of these claims should not be withdrawn, as they read on elected species, they all dependent from claims that are currently being considered, and therefore will remain in a withdrawn status.

Applicants gratefully acknowledge the allowance of claims 34-51. In doing so, withdrawn claims 36, 45, and 51 are therefore reinstated as depending from allowable generic base claims.

#### Discussion of Klein

Claims 52-53, 55-63, and 65-71 stand rejected under 35 U.S.C. §102(b) as being anticipated by Klein, et al. (USPN 5,279,565). Applicants respectfully disagree with the Examiner's reading of Klein, et al.

With regard to claim 52, Applicants assert that Klein, et al. do not disclose a tissue dissector having an elongated cannula and a distal tip having tapered outer walls, with a solid dilating element of *fixed outer dimension* disposed on the cannula proximal to the distal tip and having a cross-sectional dimension greater than the cross-sectional dimension of the distal end of the cannula and the distal tip. Instead, Klein, et al. disclose a flexible catheter body 20 having a distal fluid delivery means 28. As discussed in the paragraphs bridging columns 7 and 8, the delivery means 28 includes rigid platforms 29 coupled to the catheter by means of a support frame comprising a distal beam 52 and a proximal beam 54. As stated in column 8, lines 3-12, beams are either flexible so as to deflect radially outward, or mounted so as to pivot outward, and displace the rigid platforms 29 outward. The end result is that the rigid platforms 29 deploy into contact with surrounding tissue such that fluid may be delivered to interface 49 to impregnate the tissue. The Examiner cites beams 52 and 54 as providing the solid dilating element of fixed outer dimension. However, as just explained, the beams 52 and 54 deflect or pivot outward, and thus

Serial No.: 09/413,012  
Docket No.: R0052CON  
Amendment Dated May 4, 2006  
Responsive to the Office Action dated March 6, 2006

do not define a dilating element of fixed outer dimension. Indeed, these beams 52, 54 are not even dilating elements, neither are the rigid platforms 29. Accordingly, Applicants respectfully assert that claim 52 and its dependents are allowable over Klein, et al.

With regard to claim 63, Applicants assert that Klein, et al. do not disclose a *dilating unit*  
5 *removably mounted* on the cannula distal end including a) a distal tip having tapered outer walls converging to a blunt end for dissecting tissue and b) a dilating element located proximally with respect to the distal tip and having a cross-sectional dimension greater than the cross-sectional dimension of the distal end of the cannula and the distal tip. In the context of claim 63, the term "removably mounted" means that the dilating unit is detachable from the distal end of the cannula.  
10 As described in the specification from page 5, line 13 through page 6, line 6, a dilating unit may be conveniently removed from the distal end of the cannula by, for example, utilizing a threaded connection. Please note that it is the entire dilating unit including the distal tip and dilating held that is removable from the cannula.

In contrast, the beams 52, 54 that the Examiner identifies as corresponding to the dilating  
15 element are not removable from the device of Klein, et al. Moreover, it is abundantly clear that a "dilating unit" including the distal nose cone 26 and the beams 52, 54 is not removably mounted to the distal end of the catheter. Indeed, please note the passage at column 8, lines 20-30, where an actuator shaft 38 attaches to a distal end 60 of the nose cone 26, and the proximal beams 54 are connected at their proximal ends to fluid delivery passages. Figs. 3A and 3B appear to show  
20 the actuator shaft 38 having the same cross-section as the distal end 60, which would obviously retain the nose cone 26 on the actuator shaft 38. In any event, all of this mechanism is not "removably mounted" to the catheter. First, the actuator shaft 38 does not appear to be removably mounted from the catheter, and it retains the nose cone 26 thereon. Secondly, all of the fluid delivery passages to the proximal beams 54 and rigid platforms 29 create a structure that  
25 is not "removably mounted" to the catheter. Although these components of the device shown in Klein, et al. may be disassembled, that does not render them removably mounted.

Serial No.: 09/413,012  
Docket No.: R0052CON  
Amendment Dated May 4, 2006  
Responsive to the Office Action dated March 6, 2006

Accordingly, Applicants believe that claim 63 and its dependents are allowable over Klein, et al.

#### Discussion of Andrese

5        Claim 52 stands rejected under 35 U.S.C. §102(e) as being anticipated by Andrese (USPN 6,015,423). Applicants again note that claim 52 requires an elongated cannula and a distal tip having tapered outer walls, with a *solid* dilating element of *fixed outer dimension* disposed on the cannula proximal to the distal tip.

10        Andrese discloses a dilation catheter having a distal tip 11a comprising semi-frustoconical tips 12, 13 that open and close and are connected to the catheter body with an elastic bridging portion 14. The Examiner identifies the bridging portion 14 as corresponding to the solid dilating element of claim 52. For two reasons, Applicants assert that the bridging portion 14 is not a solid element of fixed outer dimension.

15        First, all of the embodiments disclosed in Andrese provide fluid flow apertures through the bridging portion 14; namely, the apertures 23 in the embodiment of Figs. 1-4, and the apertures 106 in the embodiment of Figs. 5-7. As stated at column 4, lines 10-15, these apertures "provide a passageway for blood or other body fluids to continue to flow through the structure even when the catheter tip is in the expanded position shown in Fig. 3. "This is characterized as an "important aspect" of the invention, and cannot be ignored. Applicants assert that the bridging  
20        portion 14 having such apertures is not "solid." Moreover, the bridging portion 14 is described as being foraminous (column 2, last line), which relates to an opening or orifice. Fig. 2 illustrates the bridging portion 14 as being a thin structure connecting the catheter body and the tips 12, 13. This is not "solid" as the dilating elements are shown in the present application. The term "solid" does not mean "not liquid," but instead means not hollow, as is a balloon.

25        Second, one function of the bridging portion 14 is to provide outer surface continuity between the tips 12, 13 and the catheter body when the tips open and close. By definition, the bridging portion 14 flexes in and out with the tips and does not have a "fixed outer dimension."

Serial No.: 09/413,012  
Docket No.: R0052CON  
Amendment Dated May 4, 2006  
Responsive to the Office Action dated March 6, 2006

Applicants assert, therefore, that claim 52 and its dependents claims are allowable over Andrese.

Conclusion

5 There are no additional claim fees or extension of time fees.

Accordingly, Applicants believe that based on the above amendments and remarks, and after any withdrawn claims are reinstated, claims 34-71 are in condition for allowance. Such action is respectfully solicited. If there is any further hindrance to allowance of the present application, the Examiner is encouraged contact the undersigned by telephone.

10

Date: May 4, 2006

15

20

Respectfully submitted,



Guy Cumberbatch, Reg. No. 36,114  
(805) 201-3006  
c/o Lena Vinitkaya, Reg. No. 39,448  
3200 Lakeside Drive  
Building B, 3<sup>rd</sup> Floor, M/S 314  
Santa Clara, CA 95054  
(408) 845-1978  
(408) 845-3987 (facsimile)